UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,568	11/07/2001	Tracy Willson	11373Z	4029

7590 08/01/2008

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, NY 11530

EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
08/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/036,568	WILLSON ET AL.	
	Examiner	Art Unit	
	NIRMAL S. BASI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,42,43,47 and 52-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37,42,43 and 47* is/are allowed.

6)☒ Claim(s) *52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2/08 and 5/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/08 has been entered.

2. Amendment filed 7/2/08 has been entered. Applicant has cancelled claims 1-36, 38-41, 44-46, 48-51, added new claims 52-54 and amended claim 37. Claims 37, 42-43, 47 and 52-55 are pending in the application and are examined below. Applicant's arguments have been fully considered and are addressed below:

Drawings

3. The drawings were received on 7/2/08. These drawings are objected to by the Examiner. There is no marked up copy of the changes made. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

The drawings also objected to for containing new matter.

4. The amendment filed 7/2/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The renumbering of the amino acid sequence in Figure 7 apparently due to the introduction of two gaps in to the sequence. Applicant argues these gaps should not be included when counting the number of nucleotides and amino acids in murine NR4. Applicant looks for support in the description of Figure 7 for support. The description of Figure 7 shows that the sequences for the human and murine IL-13 Rα were aligned by eye, with gaps inserted to optimize alignment. The specification discloses nothing about whether gaps should be included or excluded when counting the number of nucleotides and amino acid residues in murine NR4. Applicant chose to count the gaps when the application was filed. The exclusion of the gaps, when renumbering the Figure 7, is not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

5.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim incorporates new matter, "isolated polypeptide comprising amino acids 28-426 or 28-343 of SEQ ID NO:4 or comprising an amino acid sequence having at least 95% identity with amino acids 28-426 or 28-342 of SEQ ID NO:4"

Said new matter is not supported by the original disclosure. The specification discloses SEQ ID NO:4 but not the species "isolated polypeptide comprising amino acids 28-426 or 28-343 of SEQ ID NO:4 or comprising an amino acid sequence having at least 95% identity with amino acids 28-426 or 28-342 of SEQ ID NO:4". Applicant argues that with alignment of mouse mature protein of T27 to P424 of SEQ ID NO:2 with human protein (SEQ ID NO:4, NR4), one would naturally arrive at the polypeptide of composed of T28-Q426 of SEQ ID NO:4. Applicant further argue that by reviewing the alignment of the extracellular domain of mouse receptor of (T27-T340 of SEQ ID NO:2) in Figure 1 with SEQ

ID NO:4 in Figure 7, one would naturally arrive at the polypeptide composed of T28-T342 of SEQ ID NO:4. Applicants look for support for the limitation of "95% identity" on page 9, lines 1-5. Applicants argue (see page 5 of applicants' arguments) and specifically state, " Support for a polypeptide having at least 95% identity to a part of SEQ ID NO: 4 is found in the specification, e.g., on page 9, lines 1-5." The examiner can find no such support.

The last 4 lines on page 4 through the first 10 lines on page 5 are reproduced below:

> "Another aspect of the present invention provides a nucleic acid molecule comprising a sequence of nucleotides encoding IL-13 receptor α-chain having an amino acid sequence as set forth in SEQ ID NO:2 or having at least about 50%, similarity to all or part thereof. Preferably, the percentage similarity is at least about 60%, more preferably at least about 70%, even more preferably at least about 80-85% and still even more preferably at least about 90-95% or greater. The reference to all or part of a sequence is intended to include defining a hybrid molecule comprising parts of two receptors. It is not intended to encompass single amino acids.
>
> A further embodiment of the present invention contemplates a nucleic acid molecule comprising a sequence of nucleotides encoding the IL-13 receptor α-chain and having a nucleotide sequence substantially as set forth in SEQ ID NO:I or having at least about 50% similarity to all or part thereof. Preferably, the percentage similarity is at least about 60%, more preferably at least about 70%, even more preferably at least about 80-85% and still even more preferably at least about 90-95% or greater. "

Further, Figures 1 and 7 show alignments of the complete murine and human IL-13 and do not allow one to "naturally arrive" at the polypeptide species composed of the fragment T28-Q426 of SEQ ID NO:4 or "naturally arrive" at the polypeptide species composed of the fragment T28-T342 of SEQ ID NO:4, let alone polypeptide that are 95% identical thereto and bind IL-13. Applicant has

not naturally arrived at the species disclosed above but picked a series of alignments to arrive at a species they wish to claim. The first problem, the signal sequence for human IL-13 receptor was not known or deduced at the time of filing of instant application. The second problem, the signal sequence of human IL-13 receptor is not the same as murine IL-13 receptor so a direct comparison cannot not be made so as to allow one to "naturally arrive" at the polypeptide of composed of 28-426 or 28-342 of SEQ ID NO:4. Further, murine and human IL-13 receptor are 75% identical. The claims are drawn to specific species of protein which require the exact knowledge of the amino acids that make up the signal sequence of the human NR4 and those sequences that make up the soluble protein and mature protein. Although signal sequence for the murine NR4 is disclosed in the specification the signal sequence of human NR4 was not known at the time filing of instant application. The sequences of human and murine NR4 have 75% similarity but the first 26 amino acids on murine NR4 (signal sequence of murine NR4) is only 61.5% identical to human NR4. Based on the disclosure no determination can be made that both murine and human NR4 have the same signal sequence.

Comparison of the first 26 amino acids of human and murine NR4:

Human M **E** **W** P A **R** L **C** **G** G **G** **G** **G** A **P** T E **T** E N L C T V I W

Murine M **A** **R** P A **L** L **G** **E** G **Q** **V** **A** A **A** T E **V** E N L C T I I W

The question arises did the prior art conclusively predict the signal sequence and the sequence of the mature and soluble form of the NR4 without ambiguity. The answer is no. Therefore, based on this fact alone, one would not

naturally arrive at the polypeptide species claimed in claims 52 and 53. The exact nature of the "soluble form" or "mature form" of IL-13 receptor is not disclosed. If the exact size of the "soluble form" or "mature form" cannot be defined as it relates to the polypeptide disclosed in SEQ ID NO:4 then it seems highly unlikely one can arrive at the species claimed which, require the knowledge of the sequence of both forms.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 53 and 54 are rejected because they depend on rejected base claims 52 and 53 and fail to overcome the deficiencies above.

6. Claims 37, 42, 43 and 47 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nirmal S. Basi/
Examiner, Art Unit 1646

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646